
A human neural stem cell therapeutic candidate for the treatment of chronic cervical spinal cord injury

Grant Award Details

A human neural stem cell therapeutic candidate for the treatment of chronic cervical spinal cord injury

Grant Type: Therapeutic Translational Research Projects

Grant Number: TRAN1-13059

Project Objective: The objective of this award is to conduct a well-prepared pre-IND meeting with the FDA for a human neural stem cell-based therapeutic candidate (UCI191) for chronic cervical spinal cord injury.

Investigator:

Name:	Aileen Anderson
Institution:	University of California, Irvine
Type:	PI

Disease Focus: Neurological Disorders, Spinal Cord Injury

Human Stem Cell Use: Adult Stem Cell

Award Value: \$4,950,024

Status: Pre-Active

Grant Application Details

Application Title: A human neural stem cell therapeutic candidate for the treatment of chronic cervical spinal cord injury

Public Abstract:**Translational Candidate**

The therapeutic candidate is a central nervous system tissue-derived GMP line developed under DISC2-10753 with an established GMP qualified seed bank.

Area of Impact

The target is chronic cervical spinal cord injury, which represents approximately 59% of clinical spinal cord injury cases.

Mechanism of Action

Integration of transplanted human neural stem cells is likely to direct improved locomotor function by a combination of mechanisms that include the production of new myelinating cells. Transplanted neural stem cell survival, migration, and formation of new oligodendrocytes have been linked to repair capacity.

Unmet Medical Need

There are no FDA approved treatments for spinal cord injury. There are roughly 285,000 individuals living with paralysis due to traumatic spinal cord injury in the USA, with as many as 20,425 in California at a projected collective lifetime cost of \$104 billion in direct and indirect costs of care.

Project Objective

Submission of a Pre-IND and Pre-IND meeting.

Major Proposed Activities

- Establish critical process parameters for therapeutic candidate expansion and establish GMP final product bank.
- Complete pre-clinical testing of final product cells and conduct preliminary testing of assays for potency and comparability during cell production.
- Test a clinical strategy to improve engraftment and reduce rejection after allogeneic cell transplantation into the central nervous system.

Statement of Benefit to California:

We seek to develop a new human neural stem cell therapeutic for chronic cervical spinal cord injury, for which there are no approved treatments. Improvement of a single level of spine function could have a large effect, significantly impacting both quality of life and the economic burden of disease. We also seek to develop new clinical strategies for monitoring potency during cell production and allogeneic cell transplantation, broadly impacting cell based therapies for neurological conditions.

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